DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 0 4 — 0 1 0

2. STATE: CA

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
September 1, 2004

5. TYPE OF PLAN MATERIAL *(Check One)*

☐ NEW STATE PLAN ☑ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☐ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION

7. FEDERAL BUDGET IMPACT
a. FFY ~~2004-2005~~ 2004 $ ~~52.1~~ million savings
b. FFY 2005 $ 62.5 Million savings

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Supplement 2, Attachment 4.19-B, pp 1-6

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*

Replace ~~1-7 of TN 03-012~~ Supplement 2, Attachment 4.19-B, pp 1-7

10. SUBJECT OF AMENDMENT

2004 Budget Reduction for Payment Methodology for Prescription Drugs

11. GOVERNOR'S REVIEW *(Check One)*

☐ GOVERNOR'S OFFICE REPORTED NO COMMENT
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
☑ OTHER, AS SPECIFIED
The Governor's Office does not wish to review state plan amendment

12. SIGNATURE OF STATE AGENCY ~~OFFICIAL~~

13. TYPED NAME
STAN ROSENSTEIN

14. TITLE
Deputy Director, Medical Care Services

15. DATE SUBMITTED
September 30, 2004

16. RETURN TO

Department of Health Services
ATTN: State Plan Coordinator
1501 Capitol Avenue, Ste 71-4083
P. O. Box 997413, MS 4600
Sacramento CA 95899-7413

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED
September 30, 2004

18. DATE APPROVED
December 20, 2004

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
September 1, 2004

20. SIGNATURE OF REGIONAL OFFICIAL

21. TYPED NAME
Linda Minamoto

22. TITLE
Associate Regional Administrator
Division of Medicaid & Children's Health

23. REMARKS

Pen and ink changes made to blocks 9 and 7, per State's requests via email, dated November 17 and December 8, 2004, respectively.

Instructions on Back

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE: California

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES -PRESCRIBED DRUGS

PAYMENT METHODOLOGY FOR PRESCRIPTION DRUGS

The policy of the State Agency is that reimbursement for Pharmaceutical Services and Prescribed Drugs, as one category of health care or service from among those listed in Section 1905(a) of the Social Security Act that are included in the program under the plan, will be at the provider pharmacy's current charges to the general public, up to the State Agency's limits. The price providers charge to the program shall not exceed that charged to the general public. The pharmacist, to the extent permitted by law, shall dispense the lowest cost, therapeutically equivalent drug product that the pharmacy has in stock, which meets the medical needs of the beneficiary.

The methodology utilized by the State Agency, in compliance with 42 C.F.R. §§ 447.331 and 447.332, in establishing payment rates for Pharmaceutical Services (pharmacy dispensing fees) and Prescribed Drugs (dispensed drug products) to implement the policy is as follows:

A. The method used to establish maximum drug product payments is that payments for drugs dispensed by pharmacists shall consist of the state's Estimated Acquisition Cost (EAC) of the drug product dispensed plus a dispensing fee that is added to the drug product payment (see paragraph B below). The EAC is the lowest of the Average Wholesale Price (AWP) minus 17 percent, the Maximum Allowable Ingredient Cost (MAIC); the federal upper limit of reimbursement for listed multiple source drugs (called "Federal Upper Limit," or FUL), or the charges to the general public.

B. The professional fee for dispensing is seven dollars and 25 cents ($7.25) per dispensed prescription. The professional fee for legend drugs dispensed to a beneficiary residing in a skilled nursing facility or intermediate care facility is eight dollars ($8.00) per dispensed prescription. For the purposes of this paragraph B, "skilled nursing facility" and "intermediate care facility" mean as defined in Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations.

C. For purposes of this Supplement 2, the following definitions apply:

- "Average wholesale price" means the price for a drug product listed in the department's primary price reference source.

- "Direct price" means the price for a drug product purchased by a pharmacy directly from a drug manufacturer listed in the department's primary reference source.

- "Federal upper limit" means the maximum per unit reimbursement when established by the Centers for Medicare and Medicaid Services and published by the department in Medi-Cal pharmacy provider bulletins and manuals.

- "Generically equivalent drugs" means drug products with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name, as determined by the United

States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), as those drug products having the same chemical ingredients.

- "Legend drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

- "Maximum allowable ingredient cost" (MAIC) means the maximum amount the department will reimburse Medi-Cal pharmacy providers for generically equivalent drugs.

- "Innovator multiple source drug," "noninnovator multiple source drug," and "single source drug" have the same meaning as those terms are defined in Section 1396r-8(k)(7) of Title 42 of the United States Code, the National Rebate Agreement and other Federal instructions.

- "Nonlegend drug" means any drug whose labeling does not contain one or more of the statements required to be a "legend drug".

- "Wholesale selling price" means the weighted (by unit volume) mean price, including discounts and rebates, paid by a pharmacy to a wholesale drug distributor.

D. For purposes of paragraph A, the department shall establish a list of MAICs for generically equivalent drugs, which shall be published in Medi-Cal pharmacy provider bulletins and manuals. The department will update the list of MAICs and establish additional MAICs in accordance with the following:

- The department will base the MAIC on the mean of the wholesale selling prices of drugs generically equivalent to the particular innovator drug that are available in California from wholesale drug distributors selected by the department.

- The department will update MAICs at least every three months and notify Medi-Cal providers at least 30 days prior to the effective date of a MAIC.

E. The federal upper limits of reimbursement, FUL, are initiated by CMS and provided to the State Agency for implementation in the State Medicaid Manual of Instructions. Periodic revisions to Addendum A of Section 6305.3 of the Manual, which is the list of multiple source drugs and the FUL prices, and changes to those prices as disseminated by CMS.

F. Overrides to both the state and federal price ceilings are available only through a state prior approval mechanism. Prior approval is limited to those cases where the medical necessity of a specific manufacturer's brand of a drug, priced above the ceiling, is adequately demonstrated to a state consultant. The documentation of the approval is linked to the claims payment system assuring correct reimbursement for the brand

dispensed. The same system is used for approval and payment for drugs not on the state Medicaid Drug Formulary, known as the Medi-Cal List of Contract Drugs.

G. The Medi-Cal List of Contract Drugs (List), a preferred drug list, is established pursuant to Section 1927 of the Social Security Act with prior authorization required for drugs not included on the List. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations. Prior authorization is applied to certain drug classes, particular drugs, or medically accepted indications for use and doses. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

H. The Medicaid program restricts coverage of certain covered outpatient drugs through the operation of a prior authorization program. The prior authorization process provides for a turn-around response by telephone, fax, or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a 72-hour supply of medications in accordance with the provisions of Section 1927(d)(5) of the Social Security Act.

I. Previously to mitigate the higher costs of dispensing drugs to beneficiaries residing in nursing facilities, the State Agency allowed pharmacy providers to return the unused portion of a prescription for a beneficiary in a nursing facility. In order to facilitate this, pharmacy providers will be reimbursed a restocking fee equal to the professional fee for legend drugs dispensed in

a skilled nursing facility to cover the cost of restocking. Pharmacy providers are required to reimburse the State Agency through either a direct payment mechanism (e.g., check or electronic funds transfer) or a reduction in subsequent provider payments made by he State Agency. Pharmacy providers must comply with state pharmacy laws controlling the restocking and redistribution of previously dispensed drugs. Pharmacy providers are required to report to the State Agency on the drugs returned to stock on, at minimum, a quarterly basis.

DRUG REBATE PROGRAM

The State Agency is in compliance with Section 1927 of the Social Security Act. The State Agency reimburses providers of drugs of manufacturers participating in the drug rebate program and is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data to the extent allowed under the Health Insurance Portability and Accountability Act (HIPAA) in order to ensure that the Department is protecting information in accordance with HIPAA. The unit rebate amount is confidential and is not disclosed to anyone not entitled to the information for purposes of rebate contracting, invoicing and verification.

SUPPLEMENTAL REBATE PROGRAM

The State Agency negotiates supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer are separately identified from the federal rebates.

The rebate agreement between the State Agency and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS and entitled "Medi-Cal Supplemental Rebate Agreement," has been authorized by CMS.

Supplemental rebates received by the State Agency in excess of those required under the national drug rebate agreement are shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, notwithstanding a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.